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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,875	01/12/2001	Jerome L. Krupa	P1329USA	2537

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EXAMINER	
HENDERSON, MARK T	
ART UNIT	PAPER NUMBER
3722	

DATE MAILED: 10/23/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,875	KRUPA, JEROME L.	
	Examiner	Art Unit	
	Mark T Henderson	3722	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 65-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 65-75 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Faxing of Responses to Office Actions

In order to reduce pendency and avoid potential delays, TC 3700 is encouraging FAXing of responses to Office Actions directly into the Group at (703)872-9302 (Official) and (703)872-9303 (for After Finals). This practice may be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify the examiner and art unit at the top of your cover sheet. Papers submitted via FAX into TC 3700 will be promptly forwarded to the examiner.

1. Claims 15-64 and 76-90 have been canceled. Claims 65-75 have been amended for further examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not understood how the second portion of the label may cover part of the symbol, when Claim 65 (lines 1 and 2) from which Claim 70 depends from, states that the label "attaches directly to a surface of a pharmaceutical container". How can the label attach directly to the surface of the container when there is a symbol (layer) in between the label and the container (as stated in Claim 70).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 65-72, 74 and 75 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al (6,599,481) in view of De La Huerga.

Stevens et al discloses in Fig. 1-3, a single layer label (40) which can be used for pharmaceutical use (Col. 4, lines 54-57); having a first portion (A), a first side (Fig. 2) and a second side (Fig. 3), wherein the second side attaches directly to a container (20); wherein indicium is inscribed on a second portion (B) of the label; wherein a symbol (90b) is printed on the container (Note: the symbol, however, is not directly printed on the container, but is printed on a second label (70), which is placed on the container); and wherein the indicium is adjacent, and aligned with the symbol (as seen in Fig. 2)

However, Stevens et al does not disclose: a label having a first portion having an outer boundary, and a second portion extending out and away from a side and corner of the outer boundary of the first portion; indicium on the second portion identifying pharmaceutical information prescribed to a patient, wherein the indicium is a checksum of the symbol, and the checksum includes a check digit of the checksum; wherein the first portion and second portion are generally rectangular in shape; and wherein the indicium is aligned to the symbol to allow the indicium to be scanned together by a detector in order to confirm that the pharmaceutical matches the actual contents.

De La Huerga discloses in Fig. 16 and 17, a label (50) having a rectangular first portion (527) with indicia (52) and with an outer boundary (527a), and a second portion (529) extending out and away from the outer boundary of the first portion and having indicium (Col. 9, Par. 0111).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Steven et al's label to include a first portion and an extended second portion as taught by De La Huerga for the purpose of providing indicia to be easily recognizable and distinct from the main label portion.

In regards to **Claims 65**, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, the symbol and label indica can be allowed to be programed to be used to determine any result desired by the end user.

In regards to **Claims 65, 72, 74 and 75**, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide any desirable indicia on the label, since it would only depend on the intended use of the assembly and the desired information to be displayed. Further, it has been held that when the claimed printed matter is not functionally related to the substrate it will not distinguish the invention from the prior art in terms of patentability. *In re Gulack* 217 USPQ 401, (CAFC 1983). Also, in the present case, there appears to be no new or unobvious structural relationship between the printed matter and the substrate. Mere support by the substrate for the printed matter is not the kind of functional

relationship necessary for patentability. Thus, De La Huerga's label is capable of having checksum and check digit indicia for pharmaceutical purposes.

In regards to **Claim 68**, it would have been an obvious matter of design choice to make the second portion of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. Therefore, the label of Stevens et al can be any desired shape as long as the symbol is adjacent to a label portion.

In regards to **Claim 69**, it would have been obvious to one having ordinary skill in the art at the time the invention was made to extend the second portion at any desirable location from the first portion, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Therefore, the second portion of Stevens et al's label can be placed at any location as long as the indicia on the second portion is distinguishable from the first portion.

4. Claim 73 is finally rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al in view of De La Huerga and further in view of Seidl.

Stevens et al as modified by De La Huerga discloses a label comprising all the elements as disclosed in Claim 65. However, Stevens et al does not disclose wherein at least part of the label is transparent.

Seidl discloses in Fig. Fig. 1, a single layer bar code label (1) that is transparent.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Stevens et al's and De La Huerga's label with a label having transparent material as taught by Seidl for the purpose of providing the end user with seeing the containers contents while conveying information.

Prior Art References

The prior art references listed in the attached PTO-892, but not used in a rejection of the claims, are cited for (their/its) structure. Hamisch, Sr, Stevens et al ('640), and Wood disclose similar inventions.

Response to Arguments

5. Applicant's arguments with respect to claims 65-75 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark T. Henderson whose telephone number is (703)305-0189. The examiner can be reached on Monday - Friday from 7:30 AM to 3:45 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, A. L. Wellington, can be reached on (703) 308-2159. The fax number for TC 3700 is (703)-872-9302. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC 3700 receptionist whose telephone number is (703)308-1148.

MTH

October 10, 2003

A. L. WELLINGTON
SUPERVISORY PATENT EXAMINER
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